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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,028	03/22/2004	Robert Karlsson	B 521	1001
22840 7590 10/03/2007 GE HEALTHCARE BIO-SCIENCES CORP. PATENT DEPARTMENT 800 CENTENNIAL AVENUE PISCATAWAY, NJ 08855			EXAMINER GRUN, JAMES LESLIE	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 10/03/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/806,028	Applicant(s) KARLSSON ET AL.	
	Examiner James L. Grun	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2007 and 21 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 30 and 36-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 and 31-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/27/04; 11/17/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election without traverse of Group I, claims 1-35, and the species of oligonucleotides and sensors, in the paper filed 29 January 2007 is acknowledged. Claims 36-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claim 30 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 1-29 and 31-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant desires a method in which a target molecule is delivered to a solid support via a vesicular structure and the molecule is immobilized to the support in the presence of the structure. Applicant exemplifies mixtures of a single cationic detergent,

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cetyltrimethylammonium bromide (CTAB), with high concentrations of an amine-modified oligonucleotide delivered to and binding with a surface modified with carboxymethyl groups and N-hydroxysuccinimide (NHS). Applicant assumes a critical micellar concentration (CMC) for the detergent, not the mixture, and provides no evidence that a vesicular structure was formed at the concentrations of detergent and oligonucleotides used in the conditions of the experiment. In this regard, Chatterjee et al. (Biophys. Chem. 98: 313, 2002) teach that the CMC for CTAB in water or in a phosphate buffer at pH 6-8 in the presence of various biomolecules, including DNA, varies with at least pH, temperature, and the concentration of the biomolecule and can range from 2.59 - 5.56 nM, which the examiner would note exceeds many of the concentrations used by applicant asserted as containing micelles. It is also not known or in evidence whether binding to NHS disrupted in any way the association between oligonucleotides and CTAB in the mixture of applicant. Thus, in the absence of further written description and guidance from applicant, one would not be assured of the ability to practice the invention as instantly claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 5, 11-13, 19-23, 29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 2, 11-13, improper Markush language is used to claim the members of the group. The alternatives "selected from...or" or "selected from the group consisting of...and" are acceptable.

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In claim 5, "the same kind" lacks antecedent basis.

In claim 19, it is not clear how the hydrogel is "based on" dextran and what is encompassed.

In claims 22 and 23, recitations of "the ratio" lack antecedent basis.

In claim 29, it is not clear how the sensing is "based on" surface plasmon resonance and what is encompassed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9, 10, 15, 18-21, 25-29, 31, and 35 are rejected under 35 U.S.C. § 102(b) as being anticipated by Karlsson et al. (Anal. Biochem. 300: 132, 2002).

Karlsson et al. teach the invention essentially as claimed. The reference contacted a sensor surface, having a carboxymethyl-modified dextran hydrogel thereon, with mixed micelles comprising octylglucoside. The micelles complexed with an immobilized protein and contacted the sensor surface. After use, the surface was washed, leaving the immobilized protein disassociated from the components of the mixed micelles for re-use. Proteins such as the exemplified rhodopsin carry many charges, both positive and negative.

Claims 1, 4-11, 16, 26, 31, and 33-35 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Czerkinsky et al. (J. Immunol. Meth. 65: 109, 1983).

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Czerkinsky et al. teach the enzyme-linked immunospot assay for the determination of antibody-secreting cells. Cells, considered herein as vesicular structures, suspected of containing antibodies are applied to a solid phase having bound thereon a member of a specific binding pair, antigen, to bind target molecule, antibody, released from the cells. Different antigens are bound to different surfaces. Different antibodies are produced by different cells. The antibodies are bound to antigen on the solid phase surface, the cells are removed, and the bound antibodies are detected at discrete locations.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1-15, 24, 26, and 31-35 are rejected under 35 U.S.C. 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nikiforov et al. (US 5,610,287).

Nikiforov et al. contacted mixtures of cationic detergents, including cetyltrimethylammonium bromide (CTAB) (see e.g. col. 5), with oligonucleotides for immobilization onto negatively-charged solid surfaces by both covalent or non-covalent binding

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(see e.g. cols. 14-16, Table 3). Different areas of the same solid support (wells in a microtiter plate) were treated similarly or differently. After immobilization, the detergent was washed away, leaving the immobilized oligonucleotides on the surface of the solid phase. However, the presence of vesicular structures in the mixture cannot be determined by the examiner. The Patent and Trademark Office does not have the facilities and resources to provide the *factual* evidence needed in order to establish that there is a difference, in the first place, between the reagents of the prior art and those instantly disclosed and, that if there is such a difference, that such a difference would have been considered unexpected, i.e. unobvious, by one of ordinary skill in the art. The burden is upon applicant to present such factual evidence. See e.g. In re Best (195 USPQ 430 (CCPA 1977)) or Ex parte Phillips (28 USPQ2d 1302 (BPAI 1993)).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Chatterjee et al. (Biophys. Chem. 98: 313, 2002) teach micelles of cetyltrimethylammonium bromide (CTAB) and deoxyribonucleic acid.

Reddy et al. (US 5,648,213) teach conventional alternatives for binding oligonucleotides to solid supports (see e.g. col. 10).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

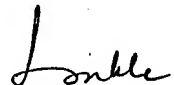
Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JLG/

James L. Grun, Ph.D.

September 20, 2007


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